



**DEPARTMENT OF HOMELAND SECURITY**  
**U.S. CUSTOMS AND BORDER PROTECTION**  
**NOTICE OF ISSUANCE OF FINAL DETERMINATION CONCERNING**  
**VARIOUS STIMULATING PROBES**

**AGENCY:** U.S. Customs and Border Protection, Department of Homeland Security.

**ACTION:** Notice of final determination.

**SUMMARY:** This document provides notice that U.S. Customs and Border Protection (“CBP”) has issued a final determination concerning the country of origin of various stimulating probes. Based upon the facts presented, CBP has concluded in the final determination that the United States is the country of origin of the stimulating probes for purposes of U.S. Government procurement.

**DATES:** The final determination was issued on February 20, 2019. A copy of the final determination is attached. Any party-at-interest, as defined in 19 CFR 177.22(d), may seek judicial review of this final determination within [INSERT 30 DAYS FROM DATE OF PUBLICATION IN THE FEDERAL REGISTER].

**FOR FURTHER INFORMATION CONTACT:** Cynthia Reese, Valuation and Special Programs Branch, Regulations and Rulings, Office of Trade (202-325-0046).

**SUPPLEMENTARY INFORMATION:** Notice is hereby given that on 02/20/19, CBP issued a final determination concerning the country of origin of various stimulating probes for purposes of Title III of the Trade Agreements Act of 1979. This final determination, HQ H300744, was issued at the request of Rhythmlink International, LLC, under procedures set forth at 19 CFR Part 177, subpart B, which implements Title III of the Trade Agreements Act of 1979, as amended (19 U.S.C. 2511-18). In the final determination, CBP has concluded that, based upon the facts presented, the processing that occurs in China does not substantially transform the stimulating probes from products of the United States to products of China. Therefore, the

stimulating probes are products of the United States for purposes of U.S. Government procurement.

Section 177.29, CBP Regulations (19 CFR 177.29), provides that notice of final determinations shall be published in the *Federal Register* within 60 days of the date the final determination is issued. Section 177.30, CBP Regulations (19 CFR 177.30), provides that any party-at-interest, as defined in 19 CFR 177.22(d), may seek judicial review of a final determination within 30 days of publication of such determination in the *Federal Register*.

Dated: February 20, 2019

Alice A. Kipel, Executive Director  
Regulations and Rulings  
Office of Trade

HQ H300744

February 2, 2019

OT:RR:CTF:VS H300744 CMR

CATEGORY: Origin

David S. Robinson, Esq.  
Nexsen Pruet  
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Raleigh, NC 27612

RE: U.S. Government Procurement; Title III, Trade Agreements Act of 1979 (19 U.S.C. § 2511); subpart B, Part 177, CBP Regulations; Various Stimulating Probes

Dear Mr. Robinson:

This is in response to your request of August 30, 2018, on behalf of your client, Rhythmink International, LLC, (hereinafter, Rhythmink) requesting a final determination concerning the country of origin of various stimulating probes for purposes of U.S. government procurement under Title III of the Trade Agreements Act of 1979 (TAA), as amended (19 U.S.C. § 2511 *et seq.*). Rhythmink is a party-at-interest within the meaning of 19 C.F.R. § 177.22(d)(1), and is entitled to request this final determination under 19 C.F.R. § 177.23(a). In addition, you have requested a country of origin determination for marking purposes.

FACTS:

Rhythmink manufactures and distributes medical devices and provides custom packaging, private labeling, custom products and contract manufacturing to its customers. It seeks a country of origin determination for purposes of government procurement under Title III of the TAA for six stimulating probes. These six probes are: the Standard Ball Tip Probe, the Tapered Ball Tip Probe, the Standard Monopolar Probe, the Extended Monopolar Probe, the Monopolar Stimulating Probe with Removable Handle, and the Slide Shaft Stimulating Probe.

The probes are produced in the United States from U.S. origin steel. You describe the processing in the United States as consisting of engineering and design work and manufacturing of the steel probes. The engineering and design work includes: research and development; design control; IP generation; regulatory clearances; specifications; engineering drawings; work instructions; tooling, fixtures, and equipment designs; functional verification testing; sterilization validation; packaging, sterile barrier, shelf life validation; and process validations. The manufacturing which occurs in the United States, by a third-party contract manufacturer, entails cutting raw stainless steel rods of 316 straight grade stainless steel to a specified length to meet specified tolerances. The stainless steel rods are cut by a precision mill or band saw. After cutting, the rods are ground to a precise diameter on a precision lathe. In addition, the lathe is used to create a taper on a portion of one end of the rod to narrow the diameter to half of the original diameter of the tip. The rods are centered precisely on the narrow rod tip and welded to a stainless steel ball to form a connection with a strength of greater than or equal to 36 pounds. The probes resulting from this manufacturing process are then subject to passivation which involves a process of cleaning the probes ultrasonically with an alkaline cleaning detergent, rinsing with deionized water, placing in an acid solution, rinsing twice in separate deionized water tanks and drying. The steel probes are then packaged and shipped to China for further processing.

In China, the probes are attached to a leadwire of Korean origin using Chinese solder, and covered with a heat shrink from China, Japan, or the United States. The probes are attached to a hand grip consisting of a U.S.-origin handle insert and a Korean origin plastic handle. You indicate that the processing in China takes less than four minutes. The finished probes are inserted into a protective cover from the United States and packaged for shipment to the United States.

You indicate that there is an insulated stimulating probe with a removable handle. For the removable handle style probe, there are only two steps performed in China: maintaining an inventory and packaging. The removable handle probe consists of three functional components: an insulated stainless steel probe (United States), a wire with DIN 42-802 connectors on each end coiled tightly (Korea or Japan), and a removable plastic handle (United States). There is no protective cover for this probe as it is secured within a durable plastic tray with a lid which serves as protective packaging. You state that all parts are packed unattached, in a plastic tray, pouched and boxed.

Upon return to the United States, the probes are subjected to a 30-hour sterilization process and subjected to a randomized sampling and testing protocol.

## ISSUE:

What is the country of origin of the stimulating probes described herein for U.S. government procurement purposes?

## LAW AND ANALYSIS:

U.S. Customs and Border Protection (CBP) issues country of origin advisory rulings and final determinations as to whether an article is or would be a product of a designated country or instrumentality for the purpose of granting waivers of certain “Buy American” restrictions in U.S. law or practice for products offered for sale to the U.S. Government, pursuant to subpart B of Part 177, 19 C.F.R. § 177.21 *et seq.*, which implements Title III, Trade Agreements Act of 1979, as amended (19 U.S.C. §§ 2511 - 2518).

The rule of origin set forth in 19 U.S.C. § 2518(4)(B) states:

An article is a product of a country or instrumentality only if (i) it is wholly the growth, product, or manufacture of that country or instrumentality, or (ii) in the case of an article which consists in whole or in part of materials from another country or instrumentality, it has been substantially transformed into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was so transformed.

See *also* 19 C.F.R. § 177.22(a).

In rendering advisory rulings and final determinations for purposes of U.S. Government procurement, CBP applies the provisions of subpart B of Part 177 consistent with the Federal Procurement Regulations. See 19 C.F.R. § 177.21. In this regard, CBP recognizes that the Federal Acquisition Regulations restrict the U.S. Government’s purchase of products to U.S.-made or designated country end products for acquisitions subject to the TAA. See 48 C.F.R. § 25.403(c)(1). The Federal Acquisition Regulations define “U.S.-made end product” as:

. . . an article that is mined, produced, or manufactured in the United States or that is substantially transformed in the United States into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was transformed.

The regulations define a “designated country end product” as:

WTO GPA [World Trade Organization Government Procurement Agreement] country end product, an FTA [Free Trade Agreement] country end product, a least developed country end product, or a Caribbean Basin country end product.

A “WTO GPA country end product” is defined as an article that:

(1) Is wholly the growth, product, or manufacture of a WTO GPA country; or

(2) In the case of an article that consists in whole or in part of materials from another country, has been substantially transformed in a WTO GPA country into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was transformed. The term refers to a product offered for purchase under a supply contract, but for purposes of calculating the value of the end product includes services (except transportation services) incidental to the article, provided that the value of those incidental services does not exceed that of the article itself.

See 48 C.F.R. § 25.003.

China is not a WTO GPA country.

In *National Hand Tool Corp. v. United States* (“*National Hand Tool Corp.*”), 16 CIT 308 (1992), *aff’d*, 989 F.2d 1201 (Fed. Cir. 1993), the court considered the nature of “substantial transformation”. At issue were sockets and flex handles which were either cold formed or hot forged into their final shape prior to importation from Taiwan, speeder handles which were reshaped by a power press after importation, and the grip of flex handles which were knurled in the United States. The imported articles were then heat treated which strengthened the surface of the steel, and cleaned by sandblasting, tumbling, and/or chemical vibration before being electroplated. In certain instances, various components were assembled together which the court stated required some skill and dexterity. The court determined that the imported articles were not substantially transformed and that they remained products of Taiwan. In making its determination, the court focused on the fact that the components had been cold-formed or hot-forged “into their final shape before importation,” and that “the form of the components remained the same” after the assembly and heat-treatment processes performed in the United States. Although the court stated that a predetermined use would not necessarily preclude a finding of a substantial transformation, it noted that such determination must be based on the totality of the evidence. The court then concluded that no substantial change in name, character or use occurred as a result of the processing performed in the United States. See also, *Superior Wire v. United States*, 867 F.2d 1409 (Fed. Cir. 1989), regarding the origin of wire rod made into wire. CBP has recently discussed the applicability of these and similar court decisions to stainless steel drill bits and other various articles exported from the United States for

finishing purposes. See Headquarters Ruling Letter (HQ) W968396, dated December 21, 2006.

In *Superior Wire v. United States*, 867 F.2d 1409 (Fed Cir. 1989), the court held that wire rod made into wire in Canada was not substantially transformed because there was no significant change in use or character. The court noted that the strength characteristic of the wire was “metallurgically predetermined” and the changes were primarily cosmetic. The court viewed the wire rod and wire as “different stages of the same product.”

In this case, U.S. steel is used in the United States to form the stimulating probes which are sent to China for further processing. We find the processing of the probes that occurs in China does not change the name, character or use of the probes. The probe with the removable handle, for instance, is packed with all parts unattached, in a plastic tray. In HQ H296072, dated July 13, 2018, CBP considered the processing of a Subdermal Needle Electrode. The processing was quite similar to the processing that the stimulating probes undergo in this case, and included soldering a leadwire to the needle electrode, adding a heat shrink and protective cover, and packaging. The stimulating probes are not substantially transformed by the processing that occurs in China. This case differs from HQ H296072 in that a handle is added to the stimulating probes.

In some cases, the attachment of a handle has been determined to be a substantial transformation, in other cases, it has not. See HQ 734521, dated September 17, 1992, for a discussion of various rulings involving the attachments of handles and the effect on the origin of the product. See *a/so*, HQ 559366, dated August 29, 1995; HQ 733804, dated November 9, 1990; and, HQ 561339, dated March 9, 2000. In this case, the handle on the stimulating probes is not necessary to the functioning of the probes, but adds to their ease of use. The stimulating probes are the essence of the products returned to the United States after processing in China. As such, we find the stimulating probes which are processed in China to attach a leadwire and hand grip, and covered with a heat shrink, are considered to be of United States origin for purposes of government procurement.

As for the insulated stimulating probe with a removable handle, which is only packaged in China, the individual parts retain their origin. Packaging of the components does not effectuate a substantial transformation.

With regard to your marking question, Section 304 of the Tariff Act of 1930, as amended (19 U.S.C. § 1304), provides that, unless excepted, every article of foreign origin (or its container) imported into the United States shall be marked in a conspicuous place as legibly, indelibly, and permanently as the nature of the article (or container) will permit in such a manner as to indicate to an ultimate purchaser in the United States the English name of the country of origin of the article. 19 C.F.R. Part

134 sets forth the regulations implementing the country of origin marking requirements and exceptions of 19 U.S.C. § 1304, along with certain marking provisions of the Harmonized Tariff Schedule of the United States (19 U.S.C. § 1202). “Country of origin” is defined, in relevant part, as: the country of manufacture, production, or growth of any article of foreign origin entering the United States. 19 C.F.R. § 134.1(b). Further work or material added to an article in another country must effect a substantial transformation in order to render such other country the “country of origin” within the meaning of this part[.]” As we have determined that no substantial transformation occurs in China due to the processing of the stimulating probes, their origin for marking purposes remains the United States. With regard to the insulated stimulating probe with a removable handle, consisting of an insulated stainless steel probe (United States), a wire with DIN 42-802 connectors on each end coiled tightly (Korea or Japan), and a removable plastic handle (United States), each component retains its individual country of origin for marking purposes. See HQ 556451, dated January 28, 1992; and, HQ 561454, dated December 14, 1999.

For purposes of marking, the stimulating probes which are processed in China are products of the United States. Because the stimulating probes are products of the United States that are exported and returned without undergoing a substantial transformation, they are excepted from country of origin marking requirements pursuant to 19 C.F.R. 134.32(m). With regard to the insulated stimulating probe that is merely packaged in China with a handle and wire connect, the origin of each component must be identified. Please note that if you wish to mark the stimulating probes, the insulated stimulating probe, or the packaging containing these products to indicate that they are “Made in the USA”, the marking must comply with the requirements of the Federal Trade Commission (FTC). We suggest that you direct any questions on this issue to the FTC.

#### HOLDING:

Based on the information provided, with the exception of the insulated stimulating probe with a removable handle, the country of origin of the stimulating probes is the United States. With regard to the insulated stimulating probe with a removable handle, which is only packaged in China, the country of origin of the individual packaged components remains unchanged.

Notice of this final determination will be given in the *Federal Register*, as required by 19 C.F.R. § 177.29. Any party-at-interest other than the party which requested this final determination may request, pursuant to 19 C.F.R. § 177.31, that CBP reexamine the matter anew and issue a new final determination. Pursuant to 19 C.F.R. § 177.30,



any party-at-interest may, within 30 days after publication of the *Federal Register* notice referenced above, seek judicial review of this final determination before the Court of International Trade.

Sincerely,

Alice A. Kipel, Executive Director  
Regulations and Rulings  
Office of Trade

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